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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,924	12/19/2001	Yanagita Toshihiko	YAM 2 0013	8207
7590	03/18/2004			
Richard M Klein Fay Sharpe Fagan Minnich & Mckee Seventh Floor 1100 Superior Avenue Cleveland, OH 44114				
EXAMINER SNEDDEN, SHERIDAN				
ART UNIT		PAPER NUMBER		
1653				
DATE MAILED: 03/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/018,924	<b>Applicant(s)</b> TOSHIHIKO, YANAGITA	
	<b>Examiner</b> Sheridan K Snedden	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13 and 15-34 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 15-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. This Office Action is in response to Paper filed 5 Feb 2004. Claims 1-12 and 14 have been canceled. Claims 13 and 15-34 are under examination.

### ***Withdrawal of Objections and Rejections***

2. Applicant's arguments have been considered and the Final Rejection mailed 1 Oct 2003 are withdrawn in favor of the following. All objections and/or rejections not explicitly restated or stated below are withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 15-19, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Adamou *et al.* (US Pub 2002/0164707 A1). Adamou *et al.* teach a adrenomedullin as a CRGP analog and agonist for CGRP receptors, which are employed for therapeutic purposes, such as the treatment of Parkinson's disease, acute heart failure, hypotension, urinary retention, and

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osteoporosis (see section [0028], [0089] and figure 9). Thus, the reference anticipates the claimed method.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adamou *et al.* (US Pub 2002/0164707 A1) in view of Kitamura *et al.* (US Patent 5,910,416).

Adamou *et al.* teach a adrenomedullin as a CRGP analog and agonist for CGRP receptors, which are employed for therapeutic purposes, such as the treatment of Parkinson's disease, acute heart failure, hypotension, urinary retention, and osteoporosis (see section [0028], [0089] and figure 9). Adamou *et al.* do not teach the modification to adrenomedullin as recited in claims 20-24 and 30-34.

Kitamura *et al.* adrenomedullin as a novel hypotensive peptide. Kitamura *et al.* teach the intravenous administration of a composition comprising adrenomedullin (see figure 3). The composition of Kitamura *et al.* comprises the peptide having the amino acid sequence from Ser13 to Tyr52, Tyr1 to Tyr52, Ala(-73) to Tyr52, and Met(-94) to Leu91 of SEQ ID NO: 2. In one embodiment of the above peptide, the carboxyl terminus of the peptide is amidated (see column 1, lines 66 and 67). In one embodiment of the above peptide, Gly is attached to the carboxyl terminus of the N-terminal peptide of proadrenomedullin (see column 2, lines 1 and 2).

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In one embodiment of the above peptide, Cys in the 16 position and Cys in the 21 position of SEQ ID No. 1 are linked by a disulfide bond, which may be substituted with a  $-CH_2-CH_2-$  bond (see column 2, lines 8-13). Kitamura *et al.* teach that adrenomedullin, and the modified versions above, have a hypotensive effect and a vasodilating effect, and therefore, they are useful in the treatment of a disease. Kitamura *et al.* provide the examples of hypertension and cardiac incompetence but fail to specifically provide an example of a urinary disorder.

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the modified adrenomedullin as taught by Kitamura *et al.* for the purposes of treating urinary retention as taught by Adamou *et al.* A person of ordinary skill in the art would have been motivated to make the above substitution because Kitamura *et al.* suggest that the modified adrenomedullin may be used as treatment in diseases alleviated by their hypotensive effect and a vasodilating effect. The person of ordinary skill in the art would have expected success because Adamou *et al.* demonstrated that adrenomedullin could be used in a method of treating urinary retention.

### ***Conclusion***

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for

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regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
March 15, 2004

A handwritten signature in cursive script, reading "Karen Cochrane Carlson".

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER